

REMARKS/ARGUMENTS

Claims 1-47 remain in this application.

Specification

1. The Examiner has objected to the specification because, according to the Examiner, the limitation of claim 18 could not be found in the specification. Paragraph 076 of the specification has, in accordance with the Examiner's recommendation, been amended to add the limitation of claim 18. No new matter has been added since the text added is found in claim 18 of the specification as filed.

2. The Examiner has indicated that the terms ALKALI BLUE, SAFRANIN, PARAROSANILINE, ALEXA FLUOR, ALEXA-488, ALEXA-633 and CY-5 have been used in this application and those "trademarks" should be capitalized whenever they occur and be accompanied by a generic terminology. In searching these terms on the USPTO Trademark Electronic Search System (TESS), Applicant was only able to identify ALEXA FLUOR as a trademark and Applicant has amended the specification to clearly identify that term as a registered trademark. ALKALI BLUE is identified as a trademark in TESS when used in combination with "BASF", that is BASF ALKALI BLUE is the trademark, not, according to Applicant's understanding ALKALI BLUE. Applicant therefore respectfully requests clarification of the Examiner's objection to the terms ALKALI BLUE, SAFRANIN, PARAROSANILINE, ALEXA-488, ALEXA-633 and CY-5 and, in particular, why the Examiner believes these terms to be Trademarks and not Names Used in Trade under MPEP § 608.01.

Claim Rejections – 35 USC §112

2. The Examiner has rejected claims 27, 28 and 33, and 44 through 47 under 35 USC §112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. However, the Examiner

has provided no explanation of why the Examiner believes that these claims are indefinite. Applicant therefore respectfully requests clarification of this rejection.

3. The Examiner has rejected claims 44 through 47 under 35 USC §112 second paragraph as being incomplete for omitting the essential steps, such omissions amounting to a gap between the steps. The Examiner then refers Applicant to MPEP §2172.01. MPEP §2172.01 provides that “a claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 USC 112 first paragraph as not enabling.” However, the Examiner has objected to the omission of steps without pointing out where, in either the specification or statements of record, those steps have been identified by Applicant as being essential. According to Applicant’s understanding this rejection is improper since the steps identified by the Examiner are not “essential steps” under MPEP §2172.01 and Applicant respectfully requests that that rejection be withdrawn. Applicant therefore believes claims 44-47 to be patentable as written.

The Examiner has rejected Claims 21 and 22 because, according to the Examiner, they contain the trademark/trade names Alkali Blue, Safranin and Pararosaliline. However, according to Applicant’s understanding as set forth hereinabove, these terms are Names Used in Trade under MPEP § 608.01 and are, therefore acceptable terms for use in Claims 21 and 22. Applicant therefore respectfully requests that the Examiner’s rejection to Claims 21 and 22 under 35 USC §112 be withdrawn.

4. The Examiner has rejected Claims 27, 28 and 33 because, according to the Examiner, they contain the trademark/trade names ALEXA-488, ALEXA-633 and Cy-5. However, according to Applicant’s understanding as set forth hereinabove, these terms are Names Used in Trade under MPEP § 608.01 and are, therefore acceptable terms for use in Claims 27, 28 and 33. Applicant therefore respectfully requests that the Examiner’s rejection to Claims 27, 28 and 33 under 35 USC §112 be withdrawn.

Claim Rejections – 35 USC §103

The Examiner has rejected Claim 1 under 35 USC §103, as being unpatentable over U.S. Patent 6,256,522 (Shultz) in view of the teaching of U.S. Patent 4,954,435 (Krauth). However, according to Applicant's understanding, neither of the cited references teach nor suggest Applicant's claimed invention as set forth in the claims rejected by the Examiner and, in particular, in Claim 1. For example, neither of the cited references teach nor suggest, alone or in combination, a device for detecting the presence of an analyte in a sample comprising a core having a binding substrate an analogue having a label with a first emission wavelength in combination with a reference having a different emission wavelength and an analyte permeable membrane that encapsulates the binding substrate, the analogue and the reference.

For example, Schultz neither teaches nor suggests a tagged analog in combination with a reference. In Schultz, both the analog and the pH indicator are used, in different embodiments, for the purpose of detecting the presence of analyte. The pH indicator in Schultz changes color when a reaction between an analyte (e.g. glucose) and a receptor (e.g. glucose oxidase) results in the creation of chemicals (e.g. gluconic acid and hydrogen peroxide) which change the pH of the interior of the capsule, thus indicating the presence of the analyte by changes in color of the pH indicator. Nor does the Schulze reference, according to Applicant's understanding, teach the combination of the pH indicator with a receptor material and an analogue material attached to a fluorescent material in a capsule as implied by the Examiner. Schultz teaches at least two different devices for the detection of an analyte. One of the devices taught by Schultz includes a dye-labeled analog-analyte within a chamber wherein fluorescent light is emitted when the detector is excited by light at an appropriate wavelength in the presence of analyte. In a second device taught by Schulz a pH detector is used to detect a change in pH indicative of the presence of analyte through the reaction of the analyte with a oxidizing agent, changing the pH of the interior of the chamber, such changes being detected by measuring the color of light reflected from the pH indicator. Nothing in the Schultz reference teaches or suggests the combination claimed by Applicant, nor does anything in the Schultz reference teach or suggest the desirability of combining a detector with a reference wherein the detector and the reference have two distinct emission

wavelengths. Nor does anything in Schultz teach or suggest, according to Applicant's understanding, any combination of pH indicator with a dye labeled analog-analyte indicator in the same detector suggested by the Examiner.

The Examiner indicates, that in the Examiner's opinion, a combination of Schultz and Krauth teach the invention as claimed in by Applicant. However, Krauth teaches a method of measuring the concentration of an analyte in an extracted sample of body fluids by indirect colorimetric detection using incident light wherein a plurality of wavelengths is directed at a liquid solution containing an analyte of interest. The solution is capable of attenuating the amount of light at first wavelength received from the solution as a function of the increasing concentration of the analyte present. A light signal from the solution to the first wavelength is detected and light at the second wavelength at which substantially no attenuation of light signal occurs as the concentration of analyte increases is also detected. The ratio of the two respected wavelengths is formed and that ratio is compared with the ratio of known amounts of analyte to determine the amount of analyte in the sample. Thus the Krauth reference neither teaches nor suggests Applicant's analog that binds to the binding cite and that is the label of the first emission wavelength in combination with a reference having a different emission wavelength than the label. In fact, Krauth teaches away from the combination suggested by the Examiner, since Krauth teaches a method of measuring the concentration of an analyte in an extracted sample using indirect colorimetric detection, which would not work in the implanted device described by Schultz.

As another example of the distinction between Applicant's claimed invention and the devices described in the references cited by the examiner, neither Schultz nor Krauth teach or suggest an analyte permeable membrane that is transparent to light at wavelengths which excite the label and the reference. Schultz teaches only a single excitation source while Krauth does not teach or suggest any permeable membrane.

Thus, according to Applicant's understanding, Applicant's claimed invention is patentably distinct from the devices described in Schultz and Krauth taken alone or in combination for the reasons set forth above. In addition, according to Applicant's

understanding, Schultz expressly distinguishes between the analog analyte embodiment (the dye-labeled embodiment) using a fluorescent dye causing light to be emitted from the dye containing analog analyte molecules and the embodiment including a pH detector in place of the analog-analyte embodiment. As Applicant has stated, nothing in any of these embodiments teaches or suggests the use of a reference in combination with the other elements of Applicant's claimed invention. Nor does this reference teach the use of an analyte permeable membrane that is transparent to light at the wavelengths that excite both a label and a reference. Nor does the Schultze reference discuss a seamless device and in fact teaches away from such a seamless device in column 6, wherein the capsule is sealed mechanically by joints plus O rings but is preferable sealed by adhesion or heat sealing, thus leaving a sealing or seam. (Also columns 7 lines 1 through 10). Nor does Krauth teach nor suggest the use of any analyte permeable membrane since Krauth is dealing with an extracted fluid sample, not an implanted device for measuring analyte.

Finally even if the combination suggested all of the elements of Applicant's claimed invention, which, they do not, the combination is taught away from by Krauth and by Schultz, since Schultz teaches a permeable membrane having only a single detection device and a means for providing a reference. It is only with impermissible hindsight that the Examiner has combined these two references by selectively taking various elements from each and combining them in a manner to the Examiner's opinion to anticipate Applicant's claimed invention.

Claim 1 being, according to Applicant's understanding, patentable over the art cited by the Examiner, those claims which depend from Claim 1 are likewise, according to Applicant's understanding, patentable over the art of record and Applicant respectfully requests that the Examiner therefore withdraw the rejection of Claims 2 to 43 under 35 USC §103.

Double Patenting

The Examiner has rejected Claims 1-43 under the judicially created doctrine of obvious type double patenting in view of Claim one of US Patent No. 6,454,710 because, according to the Examiner, Claims 1-43 of the present invention are not patentably distinct from the invention in Claim 1 of US Patent No. 6,454,710. However, according to Applicant's understanding Claims 1-43 of the present invention are patentably distinct from the invention in Claim 1 of US Patent No. 6,454,710. To take one example, Claim 1 of US Patent 6,454,710 does not include an analyte permeable membrane that is transparent to light of the wavelengths that excite the label and the reference. Thus, according to Applicant's understanding, the Examiner's rejection is not well taken and Applicant respectfully requests that it be withdrawn.

The Examiner has rejected Claims 1-43 under the judicially created doctrine of obvious type double patenting in view of Claim one of US Patent No. 6,379,622 because, according to the Examiner, Claims 1-43 of the present invention are not patentably distinct from the invention in Claim 1 of US Patent No. 6,379,622. However, according to Applicant's understanding Claims 1-43 of the present invention are patentably distinct from the invention in Claim 1 of US Patent No. 6,379,622. To take one example, Claim 1 of US Patent 6,379,622 teaches a support having an interior surface and an exterior surface and a substrate connected to the interior surface of the support. Thus, according to Applicant's understanding, the Examiner's rejection is not well taken and Applicant respectfully requests that it be withdrawn.


In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance and Applicants earnestly solicit early examination on the merits and issuance of a Notice of Allowance. Should the Examiner believe that any additional information or amendment is necessary to place the application in condition for allowance, he is urged to contact the undersigned Attorney via telephone at 408-956-4066, or facsimile number 408-956-4404.

Serial No. 09/832,663

The Commissioner is hereby authorized to charge any required fees due in connection with this submission, including petition and extension of time fees, and to credit any overpayment to Deposit Account No. 10-0750 (Docket No. LFS-5044/BES) (Johnson & Johnson).

Respectfully submitted,

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By: 
Bernard E. Shay
Reg. No. 32,061

Johnson & Johnson
International Patent Law Division
Attn: Philip Johnson
P.O. Box 1222
New Brunswick, NJ 08903
(408) 956-4066